

Exhibit 36

*Hand Copy
(Fax went thru this
morning)*

Product	Selling Unit or Package size	NDC Number	New Case Price	New Selling Unit Price	New AWP
PROCRIT® (Epoetin alfa)					
10,000 U	6 pack	59676-310-01	\$2359.20	\$589.80	\$707.76
10,000 U	25 pack	59676-310-02	\$9830.00	\$2457.50	\$2949.00
20,000 U/2ml multidose	6 pack	59676-312-01	\$4718.40	\$1179.60	\$1415.52
ORTHOCLONE OKT®3 (muromonab CD3)	5 ampule	59676-101-01	\$2900.00	\$2900.00	\$3480.00
LEUSTATIN® (cladribine) Injection	7 pack vial	59676-201-01	\$2898.00	\$414 \$2898.00	\$ 3477.60

Plaintiffs' Exhibit

237

01-12257-PBS

RECEIVED FEB 13 1997

RECVD _____
ENTRY E _____ QC KU 02114197
CODE C _____ QC _____
FILE KU 02114197 # TO CODE _____

MFTR DETD B/D-TECH
EFF DT 2/13/97
FMT 11 LAB 59676 DLAB 99962
AWP A WAE D DP Y DPPF 11.01.2
WAPF1 A - WAPF2 _____ WAPF3 _____
PTY A SCEN 1 TYPE PAT # 25679

WKH77797
CONFIDENTIAL

ORTHOBIO
ORTHOBIO

700 Rt. 202 South
Raritan, New Jersey 08869
(908) 704-5000 (Phone)

URGENT - PRICE CHANGE INFORMATION

February 12, 1997
5:00 P.M. EASTERN TIME

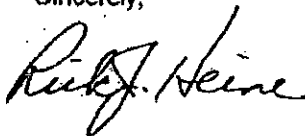
Medi-Span, Inc.
Jan Reed
8525 Woodfield Crossing Blvd.
Indianapolis, IN 46249-0930

Dear Jan:

Orders for selected Ortho Biotech Inc. products received or post marked after 5:00 PM Eastern Standard Time on Wednesday, February 12, 1997, will be billed at the new prices listed on the back of this notice.

Thank you for your cooperation.

Sincerely,



Rick Heine
Director, Trade Relations

WKH77798
CONFIDENTIAL

Feb-12-97 05:59P Ballantine Group Inc

201 209 0066

P.01

ORTHOBIOTECH

700 Rt. 202 South
 Raritan, New Jersey 08860
 (908) 704-5000 (Phone)

URGENT: PRICE CHANGE NOTIFICATION

FAX TRANSMISSION
 FAX NO. (201) 209-0066

DATE: February 12, 1997
 TO: Medi-Span, Inc.
 8525 Woodfield Crossing Blvd.
 Indianapolis, IN 46249-0930
 ATTN: Jan Reed
 FAX: (317) 469-5252
 FROM: ORTHOBIOTECH

We are transmitting 3 pages including this cover sheet.

RE: **URGENT PRICE CHANGE INFORMATION**

Effective: 5:00 (p.m.) Eastern Time
Wednesday, February 12, 1997

no Feb 13, 1997

The following notification is also being sent by Federal Express to arrive Thursday, February 13, 1997.

If there are any problems with this transmission, please contact Diane Staub at (201) 209-1616.

RECEIVED FEB 13 1997

RECVD _____
 ENTRY E MD 2-13-97 QC _____
 CODE C _____ QC _____
 FILE _____ # TO CODE _____

MFTR ORTHOBIOTECH
 EFF DT 2, 13, 97
 FMT 1447 LAB 59676 DLAB 99962
 ANP 4 WAC D DP Y #1 = 1.00
 WAPF1 A WAPF2 7 WAPF3 1.20 deuterium
 PTY A SCEN 7 TYPE 24 Bront

WKH77799
 CONFIDENTIAL

Feb-12-97 05:59P Ballantine Group Inc

201 209 0066

P.02

◆
ORTHO BIOTECH

700 Rt. 202 South
Raritan, New Jersey 08869
(908) 704-5000 (Phone)

URGENT - PRICE CHANGE INFORMATION

February 12, 1997
5:00 P.M. EASTERN TIME

(translates to 2-13-97)

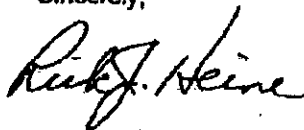
Medi-Span, Inc.
Jan Reed
8525 Woodfield Crossing Blvd.
Indianapolis, IN 46249-0930

Dear Jan:

Orders for selected Ortho Biotech Inc. products received or post marked after 5:00 PM Eastern Standard Time on Wednesday, February 12, 1997, will be billed at the new prices listed on the back of this notice.

Thank you for your cooperation.

Sincerely,



Rick Heine
Director, Trade Relations

WKH77800
CONFIDENTIAL

Feb-12-97 05:59P Ballantine Group Inc

201 209 0066

P.03

Product	Selling Unit or Package size	NDC Number	New Case Price	New Selling Unit Price	New AWP
PROCRIT® (Epoetin alfa)					
10,000 U	6 pack	59676-310-01	\$2359.20	\$589.80	\$707.76
10,000 U	25 pack	59676-310-02	\$9830.00	\$2457.50	\$2949.00
20,000 U/2ml multidose	6 pack	59676-312-01	\$4718.40	\$1179.60	\$1415.52
ORTHOCLONE OKT®3 (muromonab CD3)	5 ampule	59676-101-01	\$2900.00	\$2900.00	\$3480.00
LEUSTATIN® (cladribine) Injection	7 pack vial	59676-201-01	\$2898.00	\$2898.00	\$ 3477.60

Exhibit 37

HARD
COPY

ORTHOD BIOTECH

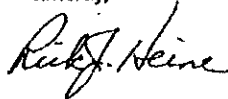
700 Rt. 202 South
Raritan, New Jersey 08869
(908) 704-5000 (Phone)URGENT - PRICE CHANGE INFORMATIONJanuary 6, 1998
5:00 P.M. EASTERN TIMEMEDI-SPAN
8425 WOODFIELD CROSSING BLVD.
PO BOX 40930
INDIANAPOLIS, IN 46240

DEAR PHARMACEUTICAL BUYER:

Orders for selected Ortho Biotech Inc. products received or postmarked after 5:00 PM Eastern Standard Time on Tuesday, January 6, 1998, will be billed at the new prices listed on the back of this notice.

Thank you for your cooperation.

Sincerely,

Rick Heine
Director, Trade Relations

WKH 02434

RECVD JAN 7 1998
ENTRY E TM 1/7/98 QC KM 0107198
CODE C QC
FILE KM 0107198# TO CODEMFTR Ortho Biotech
EFF DT 1, 7, 98 verified
FMT 11 12 LAB 59676 DLAB 99962
AWP A WAC D DP Y DPPF
WAPF1 1.00 WAPF2 1.20 WAPF3
PTY1 SCEN 7 TYPE PART# 28660

Plaintiffs' Exhibit

238

01-12257-PBS

Δ Format to 12

Product PROCRIT® (Epoetin alfa) (DPX DPF)	Selling Unit or Package Size	NDC Number	New Case Price	New Selling Unit Price DP	New AWP
10,000 U	6 pack	59676-310-01	\$2,400.00	\$600.00	\$720.00
10,000 U	25 pack	59676-310-02	\$10,000.00	\$2,500.00	\$3,000.00
10,000 U/mL x 2mL (multidose)	6 pack	59676-312-01	\$4,800.00	\$1,200.00	\$1,440.00
20,000 U/mL x 1mL (multidose)	6 pack	59676-320-01	\$4,800.00	\$1,200.00	\$1,440.00
ORTHOCLONE OKT®3 (DPX AWP) (muromonab-CD3)	5 ampule	59676-101-01	\$3,000.00	\$3,000.00	\$3,600.00
LEUSTATIN® (cladribine) Injection (DPX DPF)	7 pack vial	59676-201-01	\$3,010.00	\$3,010.00	\$3,612.00

USE PRICE
DIVISOR OF 7

WKH 02435

Jan-06-98 05:20P

P.01

♦

FAX
COPY

ORTHO BIOTECH

700 RL 202 South
Raritan, New Jersey 08869
(908) 704-5000 (Phone)

URGENT: PRICE CHANGE NOTIFICATION

FAX TRANSMISSION
FAX NO. (973) 209-0066

DATE: January 6, 1998

TO: Medi-Span
8425 Woodfield Crossing Blvd.
PO Box 40930
Indianapolis, IN 46240

ATTN: Jan Reed

FAX: 317-469-5252

FROM: ORTHO BIOTECH

We are transmitting 3 pages including this cover sheet.

RE: **URGENT PRICE CHANGE INFORMATION**
Effective: 5:00 p.m. Eastern Time
Tuesday, January 6, 1998

The following notification is also being sent by Federal Express to arrive
Wednesday, January 7, 1998.

If there are any problems with this transmission, please contact Lynn
Gustafson at (973) 209-1616.

WKH 02436

~~RECVD~~ _____

~~ENTRY E~~ _____ ~~GC~~ _____

~~CODE C~~ _____ ~~GC~~ _____

~~FILE~~ _____ # TO CODE _____

~~MFT# Ortho Biotech~~ _____

~~EFF DT~~ _____

~~FMT~~ _____ ~~LAB~~ _____ ~~DLAB~~ _____

~~AWP~~ _____ ~~WAC~~ _____ ~~DP~~ _____ ~~DPFF~~ _____

~~WAPF1~~ _____ ~~WAPF2~~ _____ ~~WAPF3~~ _____

~~PTY~~ _____ ~~SCEN~~ _____ ~~TYPE~~ _____ ~~#~~ _____

Jan-06-98 05:21P

P.02

ORTHOBIO

700 Rt. 202 South
Raritan, New Jersey 08869
(908) 704-6000 (Phone)

URGENT - PRICE CHANGE INFORMATION

January 6, 1998
5:00 P.M. EASTERN TIME

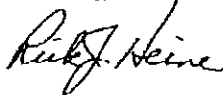
MEDI-SPAN
8425 WOODFIELD CROSSING BLVD.
PO BOX 40930
INDIANAPOLIS, IN 46240
ATTN: JAN REED

DEAR MS. REED:

Orders for selected Ortho Biotech Inc. products received or postmarked after 5:00 PM Eastern Standard Time on Tuesday, January 6, 1998, will be billed at the new prices listed on the back of this notice.

Thank you for your cooperation.

Sincerely,



Rick Heine
Director, Trade Relations

WKH 02437

Jan-06-98 05:21P

P.03

Product PROCRIT® (Epoetin alfa)	Selling Unit or Package Size	NDC Number	New Case Price	New Selling Unit Price	New AWP
10,000 U	6 pack	59676-310-01	\$2,400.00	\$600.00	\$720.00
10,000 U	25 pack	59676-310-02	\$10,000.00	\$2,500.00	\$3,000.00
10,000 U/mL x 2mL (multidose)	6 pack	59676-312-01	\$4,800.00	\$1,200.00	\$1,440.00
20,000 U/mL x 1mL (multidose)	6 pack	59676-320-01	\$4,800.00	\$1,200.00	\$1,440.00
ORTHOCLONE OKT®3 (muromonab-CD3)	5 ampule	59676-101-01	\$3,000.00	\$3,000.00	\$3,600.00
LEUSTATIN® (cladribine) Injection	7 pack vial	59676-201-01	\$3,010.00	\$3,010.00	\$3,612.00

Dup

WKH 02438

Exhibit 38

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-----x
IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION,
-----x

Civil Action: 01-CV-12257-PBS

July 28, 2004

9:40 a.m.

H I G H L Y C O N F I D E N T I A L

30(b)(6) Deposition of THOMAS HIRIAK,
held at the offices of Patterson Belknap
Webb & Tyler, before David Henry, a
Certified Shorthand Reporter and Notary
Public of the State of New York.

Henderson Legal / Spherion
(202) 220-4158

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 90

1 some, and Johnson & Johnson Health Care
2 Systems might have as well.

3 Q. Okay. I understand the
4 distribution channels, just to sum up, that
5 the -- that OBI sells to -- directly to
6 physician distributors and wholesalers who
7 then sell to end-users or customers, is that
8 correct?

9 A. That's correct.

10 Q. And what is your understanding of
11 the markets in which the wholesalers or
12 physician distributors sell into?

13 A. Physicians, hospitals, PBM's,
14 alternate sites, meaning long-term care,
15 home health.

16 Q. And what is your understanding of
17 what the drivers for marketing to physician
18 market, to the physician market? What were
19 the key selling points to the physician
20 market?

21 A. From the physician distributor
22 standpoint or from our perspective?

Page 91

1 Q. Well, does OBI have sales
2 representatives who market or who detail or
3 market to physicians?

4 A. Yes.

5 Q. And to hospitals?

6 A. Yes.

7 Q. To PBM's?

8 A. Yes.

9 Q. To home health and long-term
10 care?

11 A. Yes.

12 Q. So my question is, what is your
13 understanding as to what the drivers for
14 each of those markets is, starting with
15 physicians?

16 MR. SCHAU: You mean from OBI's
17 perspective?

18 Q. From OBI's perspective.

19 A. Clinical superiority or efficacy,
20 safety, long-term success, being in the
21 market for an extended period of time, and
22 lower cost to the health care system.

Page 92

1 Q. How about reimbursement to
2 physicians?

3 MR. SCHAU: Object to form.

4 Q. Is that a driver to the physician
5 market?

6 A. It's a driver for the physicians.

7 Q. And OBI recognizes that, is that
8 correct?

9 A. Yes.

10 Q. Okay, and has that always been
11 the case, that this has been a driver that
12 OBI is aware of in the physician market?

13 A. Specifically in oncology, yes.

14 Q. Okay. How about the hospital
15 segment? What are the drivers for the
16 hospital segment?

17 A. I would say they were saying
18 clinical efficacy, safety profile, history
19 of success for the use of Procrit, patient
20 benefits and lower cost to the health care
21 system.

22 Q. And was reimbursement of Procrit

Page 93

1 a primary consideration for a hospital?

2 A. Not as much as in physicians

3 Q. Why is that?

4 A. Many hospital pharmacists still
5 just look at cost. They look at in-patient
6 use of drugs, they look at DRG's, they look
7 at drugs as a cost center, and therefore the
8 cost message that Ortho Biotech talks about
9 I think resonates even better with hospital
10 pharmacists than it would with physicians.

11 Q. Is another end user retailers?

12 Do you still have retailers as well?

13 A. Retail is a market for Ortho
14 Biotech, yes.

15 Q. Is it for Procrit?

16 A. Yes.

17 MR. SCHAU: His question is do
18 you sell to retailers.

19 Q. No, my question was, is that a
20 market that is ultimately sold to by the
21 wholesale physicians or suppliers?

22 MR. SCHAU: Okay, fair enough.

24 (Pages 90 to 93)

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 94

1 A. Yes.

2 Q. And what are the drivers in the
3 retail market? Are they the same as in the
4 physician market?

5 A. Yes.

6 Q. And was reimbursement a
7 consideration for the retail market?8 A. Reimbursement is driven by the
9 payers that they deal with. I have to think
10 about that question for a minute.11 Q. Let me ask again. Is
12 reimbursement a primary consideration for
13 the retail market?

14 A. No.

15 Q. Okay, was it a consideration?

16 A. I think it is a consideration,
17 yes.

18 Q. And why is that?

19 A. Well, retail will know whether
20 that private payer is going to pay for
21 Procrit before they dispense the drug. They
22 know what the patient copay is when that

Page 95

1 patient walks in the door. So it is a
2 consideration because a managed care
3 organization for example, or PBN that is
4 representing an employer or a managed care
5 organization will make a decision whether
6 they will pay for it or not. Retail will
7 know what's going on, so it is a
8 consideration, but I would say more of the
9 focus would be on what a Blue Cross and Blue
10 Shield plan or whoever employer group is
11 deciding to terms of the reimbursement for
12 Procrit.13 Q. Okay. In 1991, was OBI the
14 entity that Ortho Biotech, was that the
15 entity that was marketing and selling
16 Procrit?

17 A. I believe so, but I don't know.

18 Q. Okay. Do you know what the
19 marketing strategy was in 1991 for selling
20 Procrit?

21 A. No.

22 Q. Okay, the drivers that you

Page 96

1 identified earlier for the physician
2 hospital and retail market, are those the
3 same for all the franchises?

4 A. They vary by franchise.

5 Q. They vary in degree?

6 A. Vary in degree.

7 Q. Most focus on the reimbursement
8 franchises would be oncology?

9 MR. SCHAU: Object to form.

10 Q. Which franchise recognized that
11 reimbursement was the largest driver?

12 MR. SCHAU: Object to form.

13 Q. Let me ask it another way. For
14 which franchise was reimbursement the
15 largest driver?

16 MR. SCHAU: Object to form.

17 Q. You can answer.

18 A. In the oncology market, a
19 significant portion of an oncologist's
20 revenue is from drugs. That is more in
21 oncology than it is for a nephrologist. So
22 if you are talking specifically about

Page 97

1 revenue on the part of physicians, that
2 would be oncology. But reimbursement
3 obviously is going to be a major component
4 in all markets.5 Q. And OBI was aware that the
6 oncology as well as -- okay, OBI was aware
7 from prelaunch until now that physicians or
8 hospitals in any of these franchise areas
9 were interested in the reimbursement level
10 for using Procrit?

11 MR. SCHAU: Object to form.

12 A. I don't know prelaunch, but
13 reimbursement is a major component of our
14 business.15 Q. And that's at least true back to
16 1991, will you agree with that?17 A. I don't know when the indication
18 for oncology, for chemotherapy was actually
19 introduced. If you're asking me, was it as
20 big a driving force when chronic kidney
21 disease was the focus, I would say it
22 definitely has less of a focus at that time.

25 (Pages 94 to 97)

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 154

1 McKinsey's position on that is that
2 physicians have a strong reimbursement
3 environment for Procrit.

4 Q. And this is prior to the
5 introduction of Aranesp, isn't that correct?

6 A. I believe so, yes.

7 Q. Okay. And the fact that it was
8 going to deteriorate was going to create a
9 disincentive for physicians to use Procrit.
10 Do you agree with that statement?

11 MR. SCHAU: Object to form.
12 You can answer the question if you
13 understand it, but I need to object to form
14 to preserve the record.

15 A. If you read it saying possibly
16 creating a disincentive for physicians to
17 administer Procrit, I think it is a
18 possibility, yes.

19 Q. Okay. Now, so at the time of
20 this document, was OBI aware that if its
21 physician economics deteriorated, physicians
22 may choose to use another drug?

Page 155

1 MR. SCHAU: Object to form.

2 A. This obviously is McKinsey's
3 position, so they'd have to answer exactly
4 what they wrote. I'm not sure it had to do
5 with competition, maybe it did, I'd have to
6 review the whole document, but there were
7 discussions I believe at that time with the
8 government saying that reimbursement for the
9 product was going to go down from AWP minus
10 5 to AWP minus 15. That's how I would read
11 what McKinsey is saying. Now, maybe they
12 were talking about competition. The way
13 that I read it though, that's what I would
14 take out of what McKinsey was trying to get
15 across at that time.

16 Q. Do you see any reference to the
17 change of AWP based reimbursement by
18 government in this section? That would make
19 you think that's what you're talking about?

20 MR. SCHAU: I object to form.
21 This section meaning this page?

22 MR. HOFFMAN: The executive

Page 156

1 summary.

2 THE WITNESS: Oh, just on this
3 one page, I'm sorry.

4 Q. I'm just wondering what the basis
5 is of your assumption that it's government
6 based AWP.

7 A. Well, if I read just that next
8 bullet point, range of reimbursement
9 threatened, Procrit sales growth, and then
10 it keeps going on, and then you can see down
11 there it says AWP reduction, and also APC's
12 is a reimbursement change as well. So on
13 that executive summary, yes, I do see
14 something about AWP reduction.

15 Q. Okay, but you agree that
16 physician economics prior to the
17 introduction of Aranesp was -- you agree
18 that Procrit was well positioned prior to
19 the introduction of Aranesp?

20 MR. SCHAU: Objection.

21 Q. If you can turn to page 651 on
22 this document, again that's Bates number

Page 157

1 651. Mr. Hiriak, if you can take a look at
2 that page, Bates number 651, at the top of
3 the page, it says today, physicians have
4 significant economic incentives to prescribe
5 supportive care drugs such as Procrit, due
6 to revenue and profits from stocking and
7 administering.

8 Now, my question is at the time
9 of this document, did OBI understand this
10 statement to be true?

11 MR. SCHAU: Object to form.

12 A. I don't know how you define
13 significant, but did Ortho Biotech
14 understand that reimbursement and drug
15 revenue was important to physicians, yes.

16 Q. Right. Did OBI dispute this
17 statement in any way at the time this
18 document was created?

19 MR. SCHAU: Objection.

20 A. I don't know.

21 Q. If you could take a look at page
22 659.

40 (Pages 154 to 157)

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 158

1 A. Yes.
2 Q. And at the top there it says
3 strategic evolution for Procrit, and there
4 is a category of from and to, do you see
5 that?
6 A. Yes.
7 Q. And would you agree with me that
8 the from category previously was being
9 marketed, and two, their recommendation as
10 to where it should be marketed or how it
11 should be marketed?
12 MR. SCHAU: Their being
13 McKinsey?
14 MR. HOFFMAN: Yes.
15 A. Could you ask the question again?
16 Q. Okay, let me just ask this
17 question. You see at the first bullet point
18 under from, it says used by physicians
19 because it's economically attractive, while
20 providing clinical benefits. Do you see
21 that?
22 A. Yes.

Page 159

1 Q. What period is that referring to
2 for McKinsey? What period is McKinsey
3 referring to under that category?
4 A. Period of time?
5 Q. Yes.
6 A. I would assume as of June 21,
7 1999.
8 Q. And was that your understanding
9 at the time you read this document in 1999?
10 A. My understanding that that's
11 where McKinsey was coming from?
12 Q. That that was McKinsey's
13 conclusion as to how Procrit, or why
14 physicians were using Procrit prior to 1999.
15 A. That was McKinsey's position, I
16 would assume so, again, because it's in
17 their documents, yes.
18 Q. At that time, did you understand
19 this statement to be true?
20 MR. SCHAU: The statement being
21 the first bullet point on that page?
22 MR. HOFFMAN: Yes, the

Page 160

1 statement that is in the text of the page we
2 just read.
3 A. I would question which would come
4 first, clinical benefits or economically
5 attractive, but again, did Ortho Biotech
6 understand that reimbursement and margins
7 were important to oncologists, the answer is
8 yes.
9 Q. Is it also true that Ortho
10 Biotech understood that physicians were
11 using the drug because it was economically
12 attractive?
13 A. That's why I said I would
14 question which would come first, whether
15 clinical benefits comes first or whether
16 economics come first. But again, do we know
17 that profit and margins were important to
18 oncologists, the answer is yes.
19 Q. Okay. I'd like to mark this
20 document as Exhibit Hiriak 007.
21 (Exhibit Hiriak 007, Document
22 entitled Procrit Contracting Modelling

Page 161

1 Provider Economics, marked for
2 identification.)
3 Do you recognize this document
4 entitled Procrit Contracting Modelling
5 Provider Economics?
6 A. Yes.
7 Q. Did you receive this document on
8 or about August of 2002?
9 A. I would assume so, yes.
10 Q. Do you recall the reason why
11 Charles River Associates was asked to
12 prepare this document?
13 A. I believe so, yes.
14 Q. Okay, can you tell me what that
15 reason was?
16 A. Charles River worked with us on
17 our contracting strategy. One of the issues
18 we ran into with physicians is that we as a
19 company would not market on the spread.
20 Product specialists couldn't talk about it,
21 district managers couldn't talk about it,
22 they couldn't talk about it as part of our

41 (Pages 158 to 161)

Thomas Hiriak

Highly Confidential
New York, NY

July 28, 2004

Page 226

1 A. The one that has done most of the
2 work, or almost all of the work is IBM, used
3 to be PWC and now it's IBM.

4 Q. And of the six pricing changes, I
5 believe you said six, that have taken place,
6 have all those involved third party
7 consultant analyses?

8 A. That I don't know.

9 Q. In other words does it require a
10 third party analysis to ultimately implement
11 a pricing change?

12 A. Third party, are you counting our
13 own internal finance department?

14 Q. Not in this instance.

15 A. Then I would say no, it would not
16 always have to include an outside source.

17 Q. Okay, in the internal finance
18 department, who would conduct that analysis?

19 A. Right now Doris Chern, John
20 Peterkins and ultimately Pete Patesco..

21 Q. And you said that 1997 was the
22 first price change. Can you tell me who

Page 227

1 would have worked on the internal analyses
2 from that time until now, or is it too many
3 people?

4 A. It would be difficult. I don't
5 necessarily know for 97, and the one in
6 98 --

7 Q. Let me ask you this. I'm going
8 to switch subjects. Has the price change
9 been recommended and not implemented during
10 the period 1997 to the present?

11 MR. SCHAU: Object to form.

12 Q. And I don't want to confuse you
13 with recommended.

14 MR. SCHAU: That's why I
15 objected.

16 Q. Has there been someone asked to
17 look into a price increase which didn't
18 result in price increase ultimately?

19 A. Yes.

20 Q. How many times has that happened?

21 A. Since I've been involved, I am
22 aware of one circumstance.

Page 228

1 Q. And what year was that
2 approximately?

3 A. That would have been 2002.

4 Q. And would a written analysis have
5 occurred in connection with that request?

6 A. I don't know.

7 Q. You don't know if there was any
8 kind of analysis done as to whether or not a
9 pricing change would be appropriate in that
10 instance?

11 A. I'm sorry, there was an analysis
12 done. Whether -- because of market
13 conditions, there was a decision made that
14 it would be bad timing, because the pricing
15 people, or the members of the pricing team
16 thought it would be bad timing. Their
17 recommendation was not to do anything. I
18 don't know if there was anything that was
19 written that was taken to senior management
20 at that time.

21 Q. Okay. What is contained in these
22 analyses? What factors are considered?

Page 229

1 A. I think competitive environment,
2 what's going on with the competition, their
3 price, the reimbursement environment, what's
4 going on in the reimbursement environment.
5 Obviously margins and what could potentially
6 happen to physicians' margins. Timing since
7 the last price increase, future marketplace
8 changes, what potential reaction would be of
9 our competitors or scenarios based on that,
10 if there is anything in our potential
11 contract that could mitigate the price
12 increase. Those are the things that come to
13 mind.

14 Q. Okay, and to whom is that
15 analysis presented?

16 A. Initially the pricing team.

17 Q. And what does the pricing team do
18 with those analyses?

19 A. There is a discussion that ensues
20 that shows what the belief is in terms of
21 what's going on in the environment and then
22 a decision would be made to further continue

58 (Pages 226 to 229)

Exhibit 39

ORTHO BIOTECH**Memorandum****To:** S. Walden**Date:** February 19, 1997**From:** G. Dooley *[Signature]***cc:** M. Naismith
S. Salmon**Subject:** Medicare AWP Drug Reimbursement Proposal

Sue-

Thanks for the opportunity of reviewing the draft language proposal submitted to HCFA by OMB for the Medicare AWP drug reimbursement proposal. While the fact that Medicare rebates are not proposed is certainly positive, the proposed language is of big concern as the impact on OBI would potentially be very significant.

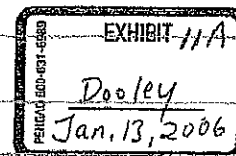
As I was in the J&J Washington office today, Shannon and I had the opportunity to discuss this and we spoke about the potential for this being a vehicle for price fixing / regulation with the obvious immediate impact on Medicare drugs, and the threat of the potential expansion to government regulation of drug prices in the future.

A few initial comments:

- The fact that the drug or biologic would not be paid on cost or prospective payment basis would imply that this is only applicable to the physicians' offices and not to clinics billed based on a cost report. (marked as line 18). We are currently seeing a shift in business for PROCRIT from the physicians' office to the clinic with one factor being the expense.
- Average Wholesale Price as specified by the Secretary seems to imply the government setting price (line 23-24).
- It appears that it would be cumbersome to submit the actual acquisition cost for each purchaser to obtain the average or actual cost.
- When the possibility of pricing surveys has occurred in the past, we have worked closely with ASCO to make sure that the actual acquisition cost is reflective of the costs incurred (i.e. syringes, storage, refrigeration, etc.). These costs are significant to the physicians' offices. I assume from the language that there is no consideration given to these indirect costs. The cost of medical and infusion supplies are considered incidental to treatment and theoretically payment is out of the windfall of the pharmaceuticals.
- Due to the fact the drugs are administered "incident to a physicians' services" under Medicare, the physician's office incurs significant up front outlay of cash - some of which may not be recovered due to wastage, spillage or indigent care.

Plaintiffs' Exhibit**979**

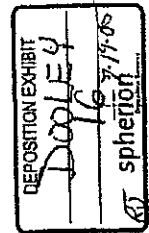
01-12257-PBS



- It is interesting that they provide a roadmap of dates for calculation as this seems to open a way to skew the system.
- Lastly, oncology practices derive a windfall from the use of chemotherapeutic agents and related drugs / biologics treating toxicities in the office setting. With this said, the difference in actual acquisition cost and what is reimbursed based on AWP may impact the use of a product like PROCRIT. This is obviously a threat for the use of a product that is may not always be considered standard of care.
- We are currently lowering our rebates to physicians and this is a step in the right direction to ensure that the acquisition price is maximized.

I would welcome your thoughts and insights on this issue and look forward to working with you on it in the future.

Exhibit 40



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Strategies for Shaping the Reimbursement Environment

ORTHO-BIOTECH, INC.

Highlights of Phase 1 findings
December 1999

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Plaintiffs' Exhibit
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INTERVIEWS CONDUCTED

Johnson & Johnson internal

Strategic customer group	Other OBI groups	Johnson & Johnson	External consultants/specialists
<ul style="list-style-type: none"> Barbara Ballard Chris Benecchi Joan Bost Arlisa Cunningham Hilton Dempsey John Dempsey Annette De'Vine Cathy Dooley Dan Dupre Cheryl Gay Tom Hiriak Ellen Ivey Elaine Kling Mary McGovern Jim Millrany Stu Mohr Rich O'Leary Bill Pearson Mark Reese Jeff Stewart Cheryl Wallace Scott Willet 	<ul style="list-style-type: none"> Tom Amick Don Cope Steve Heller Bob Honigberg Jennifer Hopwood Loretta Itri Phil Ligouri Greg Mario Dave Pierson Charlie Raffin Gary Reedy Dick Robbins Liz Scull Mitch Slavin Carol Webb 	<ul style="list-style-type: none"> Sandy Babey Syd Frank Gerald Holleman Darryl Jodrey Doug Michaels Shannon Salmon Jack Vaughn Yolanda Wallace 	<ul style="list-style-type: none"> Tom Ault, Health Policy Alternatives Nancy Bradish Myers, BIO Bobbi Buell, CEO Documedics Maureen Coleman, Practice Management Specialist Jacob Drapkin, Drapkin Associates Mark Erwin, VP Business Development at Comprehensive Reimbursement Consultants Jo Ellen Sturzberg, Cyprus Bioscience Debbie Steelman, Steelman Health Strategies Ann Vickory, Hogan & Hartson <p>Representatives of other Pharma companies</p> <ul style="list-style-type: none"> AstraZeneca Immunex Pfizer Sanofi <p>McKinsey payor/provider practice</p> <ul style="list-style-type: none"> Rick Edmunds David Levine, MD Rick Schlesinger

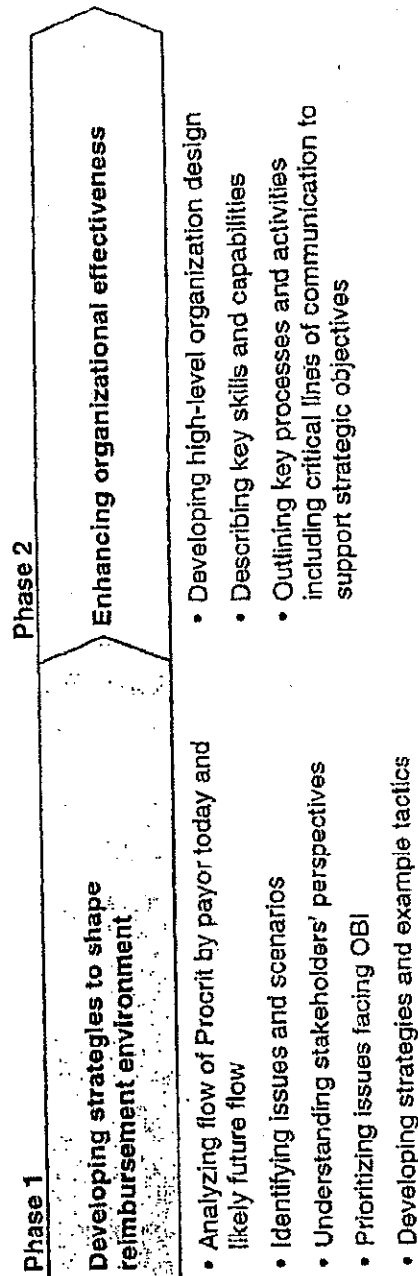
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INTERVIEWS CONDUCTED (CONTINUED)

Payors	Providers	Government agencies and other organizations
Leading private payors <ul style="list-style-type: none"> • Former Pharmacy Head • Pharmacy Head • President Specialty Healthcare • VP Pharmacy Management • Director of Formulary Management • Head of Pharmacy Management • VP Medical Management • SVP Medical Management • Case Manager 	Academic medical centers <ul style="list-style-type: none"> • Dr. Pablo Cagnoni, University of Colorado • Oncology Fellow, Memorial Sloan Kettering • Dr. Leonard, Cornell Medical Center • Dr. Rob Glasman, NYU Community Practices <ul style="list-style-type: none"> • Dr. Caruso, Stonybrook, NY • Wendy Connors, Director Case Management • Dr. Rob Geiland, NY • Nancy Kinney, Director Disease Management • Wendy McNap, Practice Administrator • Dr. Peter Yi, Princeton, NJ 	HCFA <ul style="list-style-type: none"> • Dr. Robert Berenson, Director Reimbursement group • Dr. Grant Bagley, JD, Director Coverage and Analysis Group • Dr. John J. Whyte, MPH, Medical Officer Coverage and Analysis Group • Medical Director, Medicare Carrier, BCBS Virginia/Trigon (Part A) • John Simon, Special Assistant, Health Plan Purchasing and Administration Medicare Commission <ul style="list-style-type: none"> • Bobby Jindal, Staff Director (also former head of Medicaid in Los Angeles) • Debbie Steelman, Member (also consultant) MedPac <ul style="list-style-type: none"> • Gail Wilensky, Chairman Medicaid <ul style="list-style-type: none"> • Ed Vaccaro, Pharmacy, New Jersey • Margaret Murray, Director of Medical Assistance, New Jersey • Marva Lubker, former Deputy Director Medicaid, Missouri Executive Branch <ul style="list-style-type: none"> • Bill White, White House Staff Member Intergovernmental Affairs (focus on social security, health care) American Cancer Community Center (ACCC) <ul style="list-style-type: none"> • Lee Mortenson American Society of Clinical Oncologists (ASCO) <ul style="list-style-type: none"> • Laurie Lamar, Reimbursement Specialist American Oncology Resources (AOR) <ul style="list-style-type: none"> • Russ Carson, Welsh Carson – Investor/Board Member Other <ul style="list-style-type: none"> • Debbie Cohen, Oncology book author • David Cassak, <i>In Vivo</i> magazine

PROJECT OVERVIEW



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EXECUTIVE SUMMARY – PHASE 1

As Procrit's market position continues to grow, pressure and attention to coverage and reimbursement will increase significantly, particularly for the oncology franchise. The challenge these pressures represent to the Strategic Customer Group specifically, and the OBI organization more broadly, have less to do with assisting physicians with claims coding than with developing a strategy to ensure continued top-line growth.

¶ Currently, Procrit's market position is vulnerable along two key dimensions:

- Procrit has not yet been broadly established as the standard of care
- Physician economics, while currently strong, are likely to deteriorate, possibly creating a disincentive for physicians to administer Procrit.

¶ A range of reimbursement pressures threaten Procrit sales growth. While each individually has a low likelihood of posing a major risk, the cumulative business risk is large, particularly for self administration, AWP reduction, Medicare national guidelines, and APCs.

¶ To successfully shape the outcome of these issues, OBI must move from a largely targeted, reactive strategy to one that proactively addresses a broader range of issues and constituents.

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• Procrit position today

• Reimbursement pressures

• Strategies to shape reimbursement

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OBI REVENUE BREAKDOWN - 1998 GROSS SALES

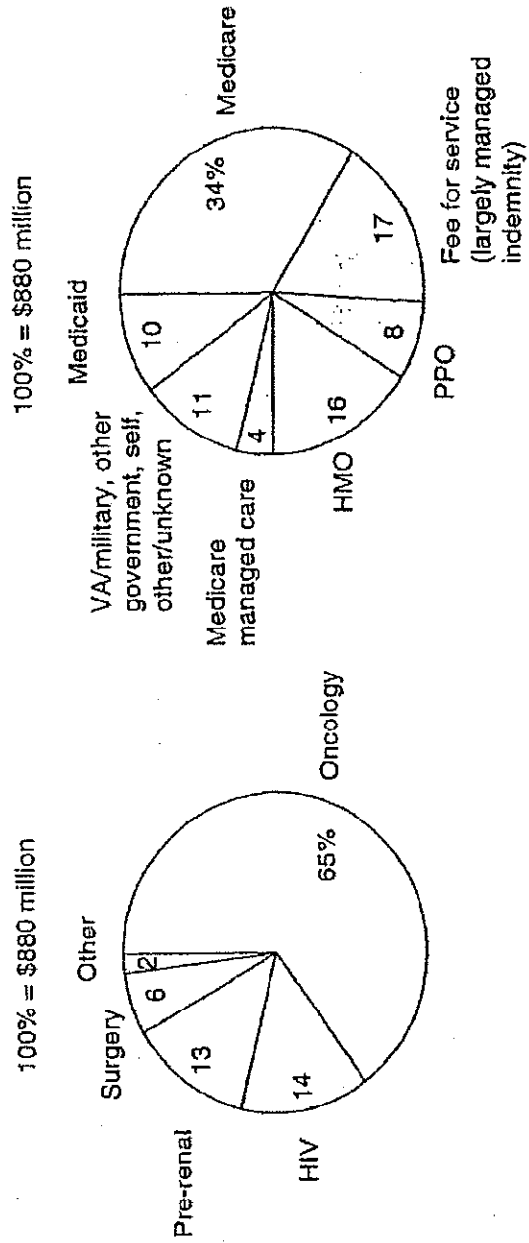
\$ Millions, percent

ESTIMATE

Private payors

Payor

Indication



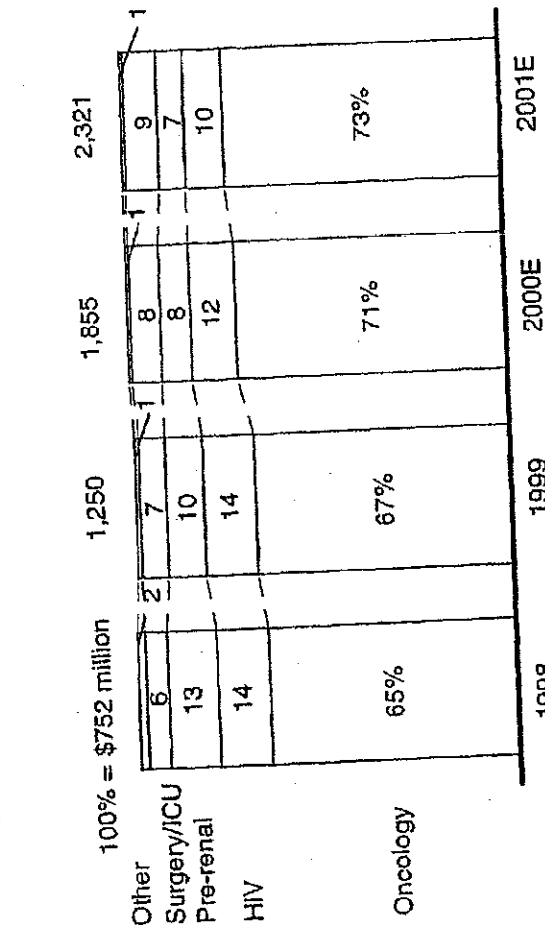
Source: Trinity Partners; Accelerated Growth Plans; Franchise Business Plans

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GROWTH OF PROCRIT SALES

\$ Millions, percent of net total

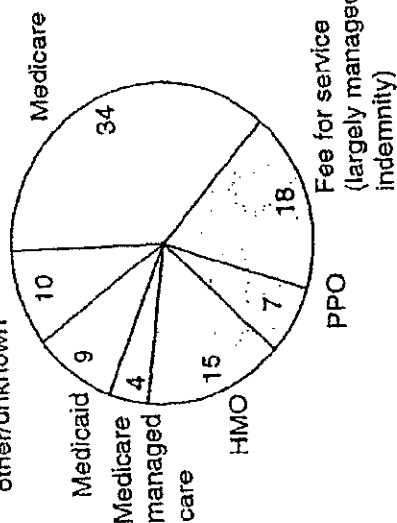


ESTIMATE

Private payors

Implied payor mix in 2001*

V/A/military, other
government, self,
other/unknown



* Based on payor mix by indication for 1998 and estimated indication mix for 2001
 Note: Growth rates for 2000 to 2001 were taken at half the previous year's rate (i.e., oncology, estimated to grow 57% from 1999 to 2000; our estimate for 2000 to 2001 is 28%)
 Source: Trinity Partners; Accelerated Growth Plan (April 22, 1999 version); McKinsey analysis

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STANDARD OF CARE SUMMARY

As yet, Procrit has not been broadly established as the standard of care in oncology among providers or payors. As a result, Procrit is not currently in a strong enough market position to withstand the reimbursement pressures that currently face it.

¶ Physicians: Questions about Procrit's clinical benefit and reimbursement concerns have led some physicians to determine use on a case by case basis, rather than as standard procedure for all patients.

¶ Payors: Procrit is not generally perceived by payors as having a sufficiently robust clinical case.

¶ Hospitals: Procrit is not universally recognized as the standard of care for chemotherapy patients by leading hospitals, nor is it cited as such by external sources.

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STANDARD OF CARE – PHYSICIAN PERSPECTIVES

There is a wide range of opinion within the physician community around the clinical benefit of Procrit

"Growth factors never saved a life... I'm not convinced they make a difference."

– Oncologist, Academic Medical Center

"I transfuse 40 to 50% of my oncology patients so I don't use much Procrit"

– Community Oncologist

"Academic physicians don't believe supportive care drugs are standard of care."

– Community Oncologist

Procrit use is often determined case by case

"Quality of life issues are addressed on a case-by-case basis, rather than broadly applied... All interventions must have a cost/benefit rationale."

– Case Manager

"For supportive care drugs, the economics come more into play... When patients have managed care plans I'm particularly stingy about prescribing."

– Community Oncologist

"Prescribing of growth factor is at the physician's discretion... No real guidelines are in place... The only real trigger is if blood counts are low."

– Oncology Fellow, Academic Medical Center

"Most community physicians rely on their own experience (to determine standard of care)."

– Community Oncologist Center

Source: Physician Interviews

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EXTERNAL PERSPECTIVES ON PROCRIT AS STANDARD OF CARE

EXAMPLES

● High
○ Medium
○ Low

Sources	Strength of Procrit position	Comments
<ul style="list-style-type: none"> National Cancer Institute PDQ (comprehensive cancer database) <ul style="list-style-type: none"> - Patient brief on supportive care: fatigue - Health professional brief on supportive care: Fatigue 	○	<p>No mention of Erythropoietin</p> <p>"Although fatigue is one of the most prevalent symptoms in cancer, there are few pharmacologic interventions with proven efficacy in clinical trials"</p>
<ul style="list-style-type: none"> Clinical pathways <ul style="list-style-type: none"> - Georgetown University Medical Center, M.D. Anderson, Allagheny University Hospital - Memorial Sloan Kettering 	○	<p>Start treatment at Hb < 11</p> <p>"I don't know of any established clinical pathway for Procrit." - Oncology Fellow</p>
<ul style="list-style-type: none"> ASCO ACCC 	?	<p>Clinical guideline under development to be released Spring 2000</p> <p>Per Georgetown University Medical Center</p>
<ul style="list-style-type: none"> Compendia (USP, AHFS) 	○	<p>Largely as per label with minimal off-label uses</p>
<ul style="list-style-type: none"> Medical texts <ul style="list-style-type: none"> - Goodman and Gillman's <i>The Pharmacologic Basis of Therapeutics</i> - <i>Cancer Principles and Practice of Oncology</i>, Devita 	○	<p>"Erythropoietin also can ameliorate the anemia associated with cancer chemotherapy."</p> <p>"Clinician needs to look for treatable causes of anemia, such as iron deficiency or blood loss, consider the underlying illness and other factors to determine if a course of EPO treatment is warranted."</p>
<ul style="list-style-type: none"> Peer-reviewed clinical literature 	○	<p>Transfusion triggers (and related role of Procrit) under debate</p>
<ul style="list-style-type: none"> Cancer Care Ontario practice guidelines (Literature review based) 	○	<p>"For cancer patients ... in whom symptoms of anemia sufficient to require red cell transfusion are anticipated, and where transfusion is not considered on acceptable treatment option, EPO can be recommended as a safe, effective treatment alternative"</p>

Source: Literature search; interviews

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STANDARD OF CARE – PAYOR PERSPECTIVES

Payors are looking for compelling clinical evidence before making a drug standard of care

"Clinical evidence is the foundation. Evidence-based medicine is our number one criteria."

– VP Pharmacy Management, Leading Health Insurer

"There will never be a reimbursement issue for drugs that are clearly needed for clinical reasons."

– President of Specialty Healthcare, Leading Health Insurer

"Internal committees review the weight of the evidence and then make a coverage decision."

– Head of Pharmacy, Leading Health Insurer

"Try to insure that the right patient gets the right drug at the right time."

– Director of Formulary Management, Leading Health Insurer

Procrit is often mentioned (unprompted) as a drug without a sufficiently robust clinical case

"Off-label uses of Epogen are unsupported by clinical data."

– Head of Pharmacy, Leading Health Insurer

"I would really worry about the medical necessity issue. Payors will be asking: 'Do you really need Neupogen, Procrit, Zofran, etc.?'"

– Reimbursement Consultant

Compounded by Procrit's status
as a supportive care drug

8 of top 10 Medicare states require
Hb<10.5 for oncology use

Source: Payor/consultant interviews

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ONCOLOGIST ECONOMICS SUMMARY

- ¶ Today, physicians have significant economic incentives to prescribe supportive care drugs such as Procrit, due to revenue and profits from stocking and administering.
- ¶ For supportive care drugs, patient insurance status often influences prescribing. Physicians tend to determine the source of Procrit (e.g., own stock versus pharmacy) and site of care depending on expected reimbursement outcomes.
- ¶ The large number of Procrit accounts below \$250,000 suggests that some oncologists either do not want to hold the financial risk, or do not fully understand the profit potential of using Procrit, this implies a significant opportunity for OBI to increase penetration.
- ¶ Despite this opportunity, a number of external pressures such as medical to pharma switch, could significantly erode physician profitability.

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ONCOLOGIST ECONOMICS – INTERVIEW FINDINGS

For private practitioners, stocking and administering Procrit yield significant profit opportunities

"Epogen is a great profit maker."

"I stock both Neupogen and Epogen and do high volumes of both. They're profit makers -- Medicare covers both and it's relatively easy to get paid for it."

"My practice makes \$6-8,000 per month on Procrit."

"The money is in ancillary services such as injectable drugs."

For supportive care drugs, patients insurance status influences prescribing... physicians tend to steer their patients depending on their insurance coverage

"I look at the patient's insurance and think about the risk I'm taking...I worry about whether I'll get paid by the insurer, so it really depends on who's covering the patient."

"My concern is less for making money and more for losing money on big investments...so I try to insulate myself by sending the more restricted patients to the pharmacy or outpatient hospital clinic."

"My Medicare reimbursement is excellent because I automatically get 80% from Medicare, and I typically get most of my other 20% in copays."

Source: Oncologist interviews

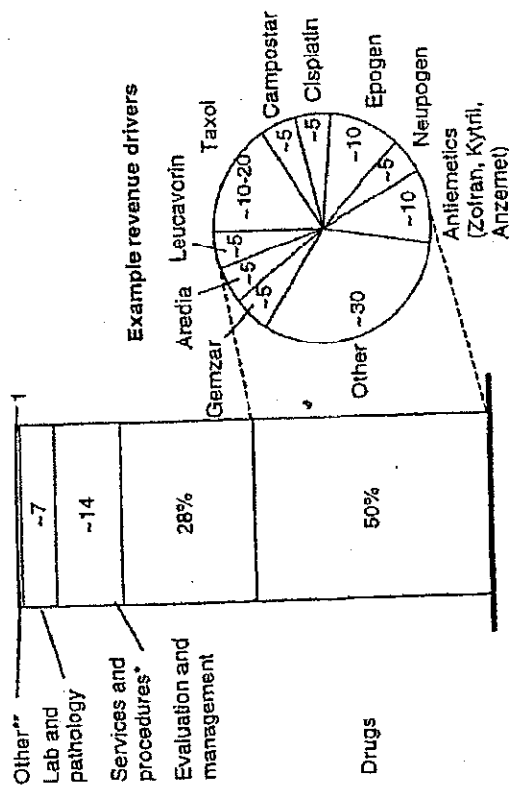
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ONCOLOGIST ECONOMICS

Average total revenues = \$1,700,000



* Includes injections, immunizations, and chemotherapy administration

** Includes procedures/diagnostic tests

*** Analyzed from 8 oncology practices

Note: Actual drug cost to practices is typically AWP ~ 20%

Source: Community Oncology Practice; Health Care Inc. data from 10 oncology practices; McKinsey analysis

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ESTIMATE

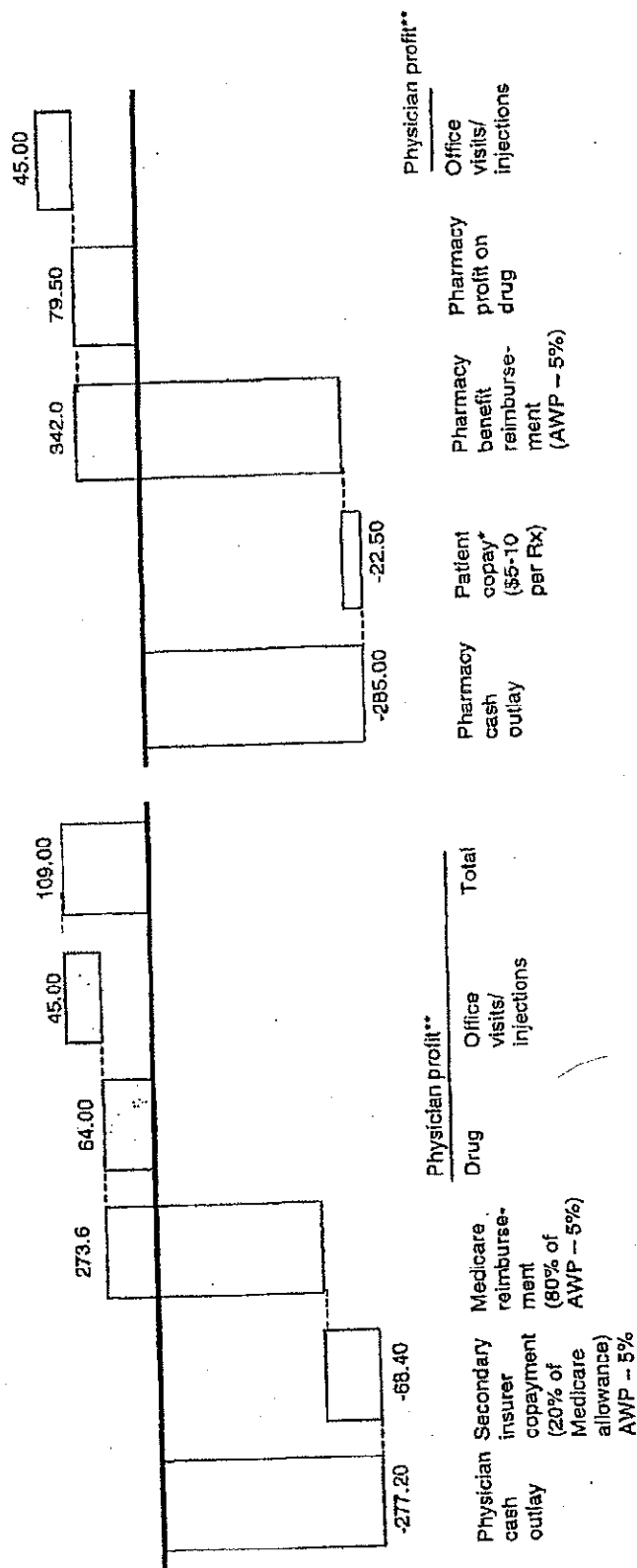
Drug	Profit***		Billing	
	Average margin	Range	Average charge	Range
Epogen (1,000 units)	29%	5 to 55%	\$15.40	\$11 to 26
Neupogen (300 mcg)	18	5 to 36%	\$171.60	\$152 to 208
Zofran (1 mg)	35	14 to 50%	\$7.70	\$6 to 11
Kytril (100 mcg)	14	-7 to 32%	\$22.60	\$19 to 35
Taxol (30 mg)	12	-1 to 28%	\$203.30	\$173 to 291

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CASE EXAMPLE**PHYSICIAN ECONOMICS FOR MEDICARE PATIENT PER WEEK**For 3 X 10,000 unit dose
Dollars

Procrit from pharmacy/PBM

Procrit from own stock



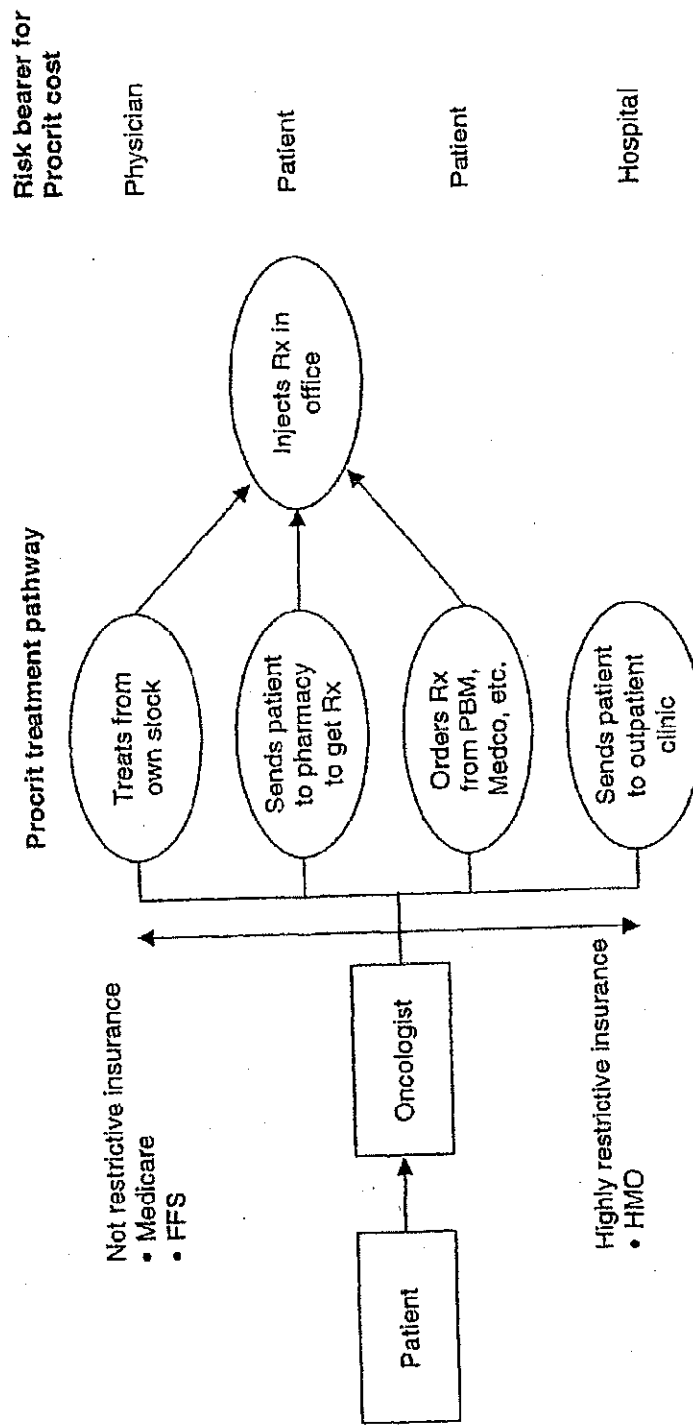
* Roughly 90% of patients have copays of \$5-10; rest have 30/20% deals
 ** Assuming payor pays for all 3 visits a week (often depends on payor), and typical practice overhead is 50% of revenues for office visits and injection fees

Note: Medicare allowance is \$120.00

Source: Community Oncology Practice

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ONCOLOGY PATIENT TREATMENT PATHWAYS



Source: Physician Interviews

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- Procrit position today

- Reimbursement pressures

- Strategies to shape reimbursement

NJ-1010.325/391006NmicSO1

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SUMMARY OF REIMBURSEMENT PRESSURES

¶ OBI faces a myriad of reimbursement pressures which could affect different indications and patient payor groups. These pressures can be prioritized based on size of potential sales impact and likelihood of occurrence over the next three years.

¶ The pressures with the highest potential sales impact and greatest likelihood of being on the agenda or occurring are:

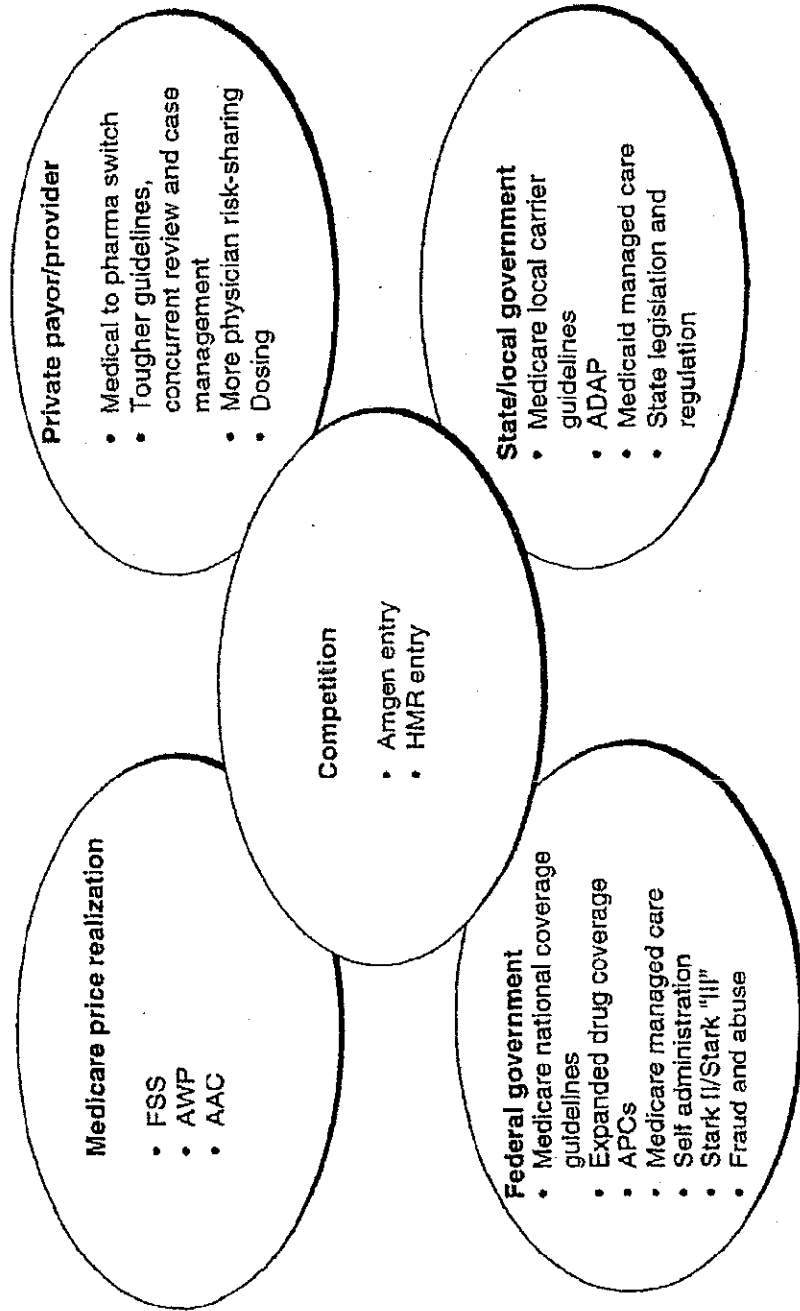
- Increase in AWP discount up to an additional 10%
- *Ambulatory Payment Classification (APCs)*
- Medicare national coverage guidelines
- *Self administration*
- Competitor impact on payor and hospital formularies.

¶ In addition, there are additional pressures with a lower likelihood of occurrence but high potential sales impact which should be monitored on an ongoing basis:

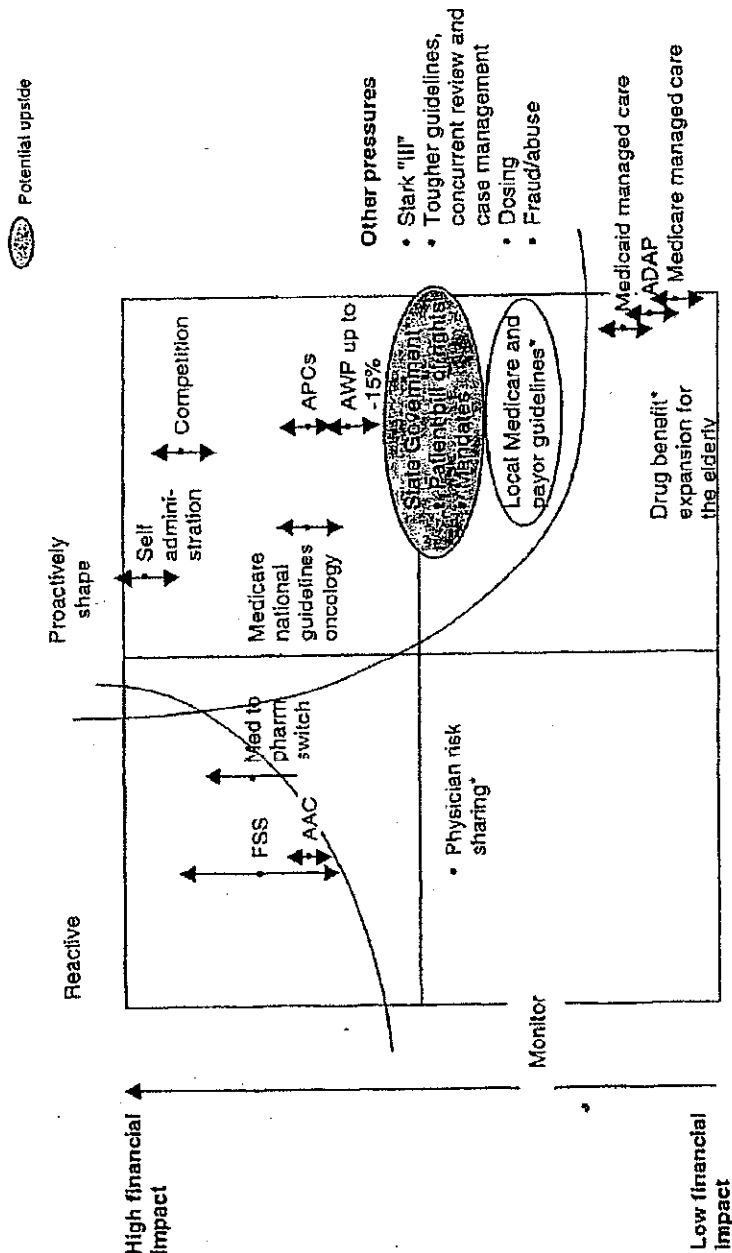
- Federal Supply Schedule (FSS)
- Actual Acquisition Cost (AAC)
- Medical to pharmaceutical switch.

¶ While the probability of any one of these pressures occurring may be low, the magnitude of the probability adjusted impact strongly suggests that investment today is vital to protect OBI's strategic and financial position.

OVERVIEW OF REIMBURSEMENT PRESSURES



PRIORITIZATION OF REIMBURSEMENT PRESSURES



Low likelihood of being on key stakeholders' agenda over next 3 years

High likelihood of being on key stakeholders' agenda over next 3 years

* Have not conducted valuation analysis

Source: Interviews; Accelerated Growth Plan; Trinity Partners; McKinsey analysis

NJ-1010.325/991006NmcSO1

UNIT PRICE REALIZATION – MAY 1999 PERSPECTIVES

Key Findings

- AWP-10% is the most likely scenario to occur
 - "I'd bet on some form of AWP modification. It's so much easier. AWP-10% is most likely"
 - Leading health care lobbyist
- "AWP-17% probably can be beat; but AWP-10% ... it's easier than defining AAC or going to FSS"
 - Former HCFA official
- FSS is unlikely to be implemented in the near term, but will not disappear
 - "This may just not be our most important battle right now ... Rather than take on the industry en masse, I think we may see one-off actions against select drugs"
 - HCFA official
 - "Votes are not there this time around"
 - Former HCFA official
- AAC is a dead issue
 - "I don't think we have the votes"
 - White House Staff in Interdepartmental Affairs
 - "We've got Y2K and much bigger issues"
 - HCFA official
 - "Defining AAC is not easy and not worth the effort when you can just do an AWP change."
 - Former HCFA official

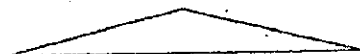
- Of all the pricing scenarios, AWP minus 10% appears to be the most likely outcome in the next 1-3 years; it certainly will receive attention and discussion and must be influenced
- FSS has huge dollar impact and must continue to be monitored

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APCs ~ MAY 1999 PERSPECTIVES

Key Findings

- Once implemented APCs could decrease hospital out patient clinic sales by \$30 to \$50 million (1999 sales)
 - Currently delayed due to a systems development hold at HCFA, pending resolution of Y2K issues
 - Once finalized, Medicare will likely implement immediately; private payors are likely to follow quickly
 - Significant opposition around bundling and assignments within system suggest there will be further revisions
 - "MedPac and others have serious concerns about the various bundlings in APC. There is still more to be done before this should be implemented."
- Former HCFA Official
- Broad consensus within the cancer community to encourage cancer carve-out as per Center for Patient Advocacy legislation
 - Six payors currently use the APC system, e.g., Blue Shield of California and Iowa Medicaid
 - Based on Blue Shield of California experience, APCs could cause shifting of patients from oncology clinics to inpatient hospital settings

- 
- Despite the slower pace and anticipated revisions, APCs appear likely to happen
 - Implementation expected to occur within 2 to 3 years
 - Private sector likely to follow once HCFA starts implementing; many already looking at ways (including APCs) to do this

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MEDICARE NATIONAL COVERAGE – MAY 1999

Key Findings

- Medical advisory committee (MCAC) will likely replace local decision making on roughly 10-20 decisions per year
- Drugs examined will likely be new or existing products with:
 - Scientific or medical controversy
 - Major impact on Medicare
 - Broad public controversy
- Any individual can initiate a request for review through formal request
- Once implemented local carriers must adhere to guideline; meanwhile, local carriers have full autonomy
- Congress may also play a role through targeted legislation
- HCFA continuing to encourage interaction among local carriers through carrier working groups, etc.
- Number of local carriers likely to decrease as HCFA encourages consolidation and local carriers exit business due to growing concerns about fraud and abuse (e.g., fines paid by Blue Cross of Illinois)

- Given Procrit's increasing impact on Medicare budgets, reasonable chance that a Procrit guideline is considered in next 3 years
- OBI should coordinate approaches across franchisees to ensure, at minimum, oncology outcome is "favorable"
- State and local oncology guidelines should be managed in the interim as they could be used later to affect national guidelines
- Private payor guidelines also need to be actively managed as they could be used later to affect national guidelines

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STATE LEGISLATIVE AND REGULATORY ACTIVITY - MAY 1999 PERSPECTIVES

- "The Virginia bill illustrates the potential for the pharmaceutical industry to benefit from 'patients' rights' bill on the state and federal level."
 - "The Pink Sheet"
- "If I were a product company, there is going to be a lot of legislation on both the federal and state level that I would be involved in."
 - HCFA official
- "There are 48 proposals in 23 states about pharmacy benefit for the elderly and typically for outpatient drugs. This is one of the few areas with upside coverage mandates"
 - J&J State Relations
- "We are putting in a variety of hard edits and prioritization guidelines to slow down the rising cost of pharmaceuticals. We are also looking at guideline opportunities in the clinical and hospital setting."
 - Medicaid official
- "Even if Breau doesn't pass on the federal level, numerous states are adding additional coverage for senior pharmaceutical assistance programs."
 - Reimbursement consultant
- "I believe that there will be substantial activity at the state level, particularly given that there will be lots of talk but little action at the federal level."
 - Former HCFA administrator
- "Most drug companies do not realize that I do worry about what the insurance commissioner thinks about my plans and the benefits included since he regulates my industry."
 - President of Specialty Business/Head Medical Management, Major private payor

- Increase in State legislative activity affecting coverage

- Substantial changes are occurring and likely to continue affecting both Medicaid and private health plans

- State legislature appears more active than regulatory agencies (e.g., Department of Insurance) but these agencies are still influential

- One of few areas with true upside potential

- State and federal legislation interlinked necessitating shaping activity at both levels

CASE EXAMPLE – VIRGINIA**1999 Legislative and Regulatory activity****New mandates****Several mandated benefits now required, examples include:**

- Hospice care
- Annual pap smears
- Equipment supplies and outpatient self-management training and education including medical nutrition therapy, for the treatment of diabetes
- Coverage for cancer pain management medications
- Coverage of clinical trials for certain cancer treatment

Access**Several new laws were designed to increase direct access including:**

- Standing referral for cancer pain management
- 24 hour telephone access to patients who must gain pre-authorization treatment approvals

Formularies**Also enacted were new measures that broadly regulate drug formularies in health plans. Among the new measures is the requirement that health plans:**

- Not deny coverage for any drug prescribed to treat a covered indication so long as the drug has been approved by the USFDA for at least one indication and the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature

Expansion of Medicaid managed care

- Medicaid II, Virginia's HMO program for Medicaid recipients expanded to Central and Eastern shore region

Vetoed bills

- Right to sue HMO directly for denial of treatment

Source: Literature search; interview with Virginia payor

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LOCAL LEGISLATION/REGULATION – MAY 1999 PERSPECTIVES

- "Medicare carrier local decision authority is not disappearing with the Medicare Coverage Advisory Commission because they will only deal with a limited number of issues. Still, we are trying to encourage carriers and medical directors to work together where appropriate and share information; decisions by one local carrier will very likely impact other local carriers."
 - HCFA official
- "In the absence of a specific national coverage decision, coverage decisions are made at the discretion of the local contractors."
 - HCFA, 4/22/99 General Notice re: Procedures for Making National Coverage Decisions
- "We're just getting started, but we're going after expensive drugs that are used in both the hospital and physician setting."
 - Director Formulary Management, private payor
- "Local health plans involved with managed Medicare and managed Medicaid have freedom to put in guidelines, particularly prior authorization."
 - Medicare Office of Health Plan Purchasing and Administration

- On a market by market basis, Procrit could get scrutinized, particularly as expenditures increase
- There are a range of influencers from case managers to medical directors that OBI will need to call on
- Local legislation and regulations are linked to federal activities

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MEDICAL TO PHARMACEUTICAL SWITCH – MAY 1999

Key findings

- Leading private payors do not generally differentiate management of pharmacy benefit (as opposed to payment) between medical and pharmaceutical benefit
 - Only a subset of products are likely to switch. Those will tend to be generally expensive, biotech, injectable and/or have high potential for abuse
 - Switch to pharma benefit unlikely without more prevalent self-administration (with or without label change)
 - Likely minimal impact on patient out-of-pocket costs for most indications since most plans have annual caps and use of other drugs hits caps rapidly
 - If implemented, patient compliance likely to decrease somewhat due to inconvenience and reluctance to self-administer
 - Switch to pharma benefit difficult without concurrent self-administration due to systems complexities of tying dispensing, billing, and auto adjudication into physician offices or hospital clinics
 - For switch to be meaningful, payors must act in a coordinated manner
- While revenue impact is large, approximately \$250 million primarily from Medicare sales, most stakeholders lack either the incentive or the ability to drive the switch on their own
 - A few "triggers" could increase likelihood such as:
 - Significant improvement in payor systems
 - Private payors reducing Procrit fee schedules and physicians choosing to hold less risk
 - Addition of self-administration to label

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- Procrit situation today

- Reimbursement pressures

- Strategies to shape reimbursement

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SUMMARY OF STRATEGIES TO SHAPE REIMBURSEMENT

To date, OBI has largely taken a reactive posture with regard to reimbursement issues. Given the diverse nature of the pressures the company is likely to face over the next three years, OBI must adopt a much more aggressive stance. Achieving this will require continuous reprioritizing of the pressures and allocating resources based on where they are likely to have the greatest impact. This will allow the organization to:

- ¶ Establish Procrit as the standard of care in oncology to all parties
- ¶ Address the interlinked private/state and federal payor systems
- ¶ In addition to Medicare, focus more on private payors and oncology
- ¶ Push more aggressively to position Procrit in a preferred position with payors.

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STRATEGIC EVOLUTION FOR PROCRIT

☐ Not focus
of this effort

From		To
<ul style="list-style-type: none"> Used by physicians because it is economically attractive, while providing clinical benefits Covered by payors but with restrictions and concerns 	→	<ul style="list-style-type: none"> Considered by physicians, patients, and payors to be absolutely vital in the treatment and recovery of patients
<ul style="list-style-type: none"> Primarily focus on expanding the marketplace 	→	<ul style="list-style-type: none"> Focus on marketplace and competitor entry <ul style="list-style-type: none"> Strong formulary position based on safety and efficacy
<ul style="list-style-type: none"> Primarily Medicare – federal focus 	→	<div style="border: 1px solid black; padding: 5px;"> <ul style="list-style-type: none"> Pricing strategy Other late lifecycle strategies </div>
<ul style="list-style-type: none"> Reactive response with little differentiation of resources by magnitude of opportunity/threat 	→	<ul style="list-style-type: none"> Focus on both public (federal, state, and local) and private constituents
<ul style="list-style-type: none"> Little proactive planning and coordination across the business system or J&J on reimbursement issues 	→	<ul style="list-style-type: none"> Frequent reprioritization of issues and resource allocation based on sales impact and likelihood of occurrence Reimbursement group playing central role in dosing, formulation, trial design and new indication decisions Explicit proactive planning and communication across J&J

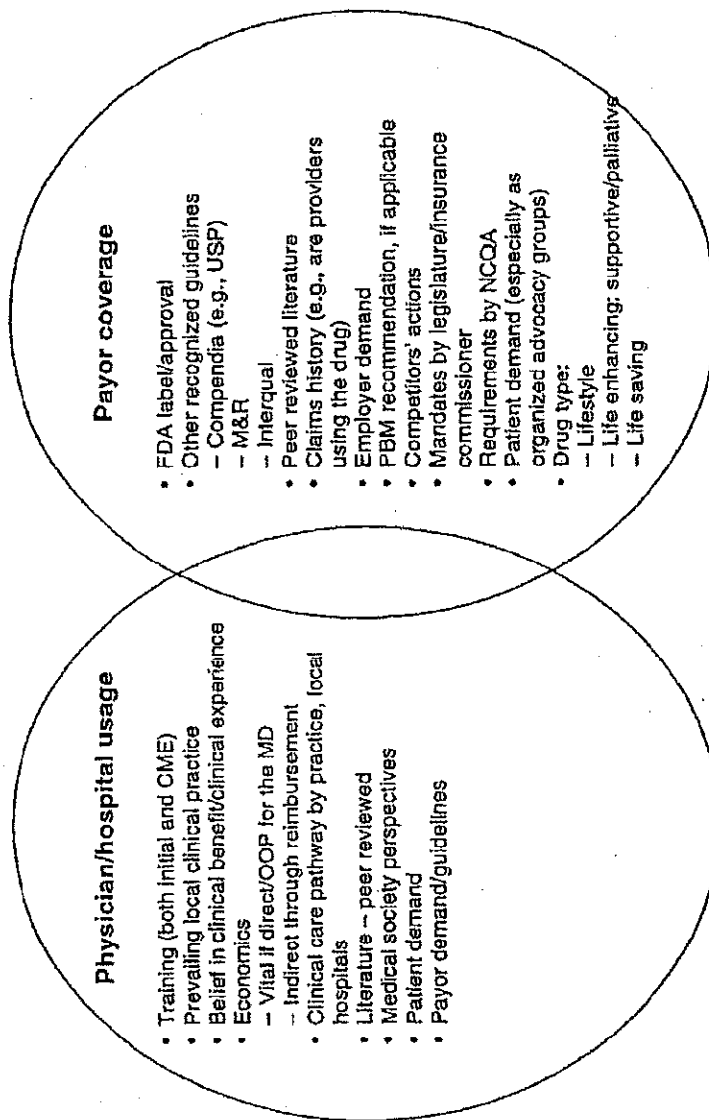
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STANDARD OF CARE – TWO LINKED ARENAS

**Procrit status:**

Not a standard of care for many physicians or institutions

Most payors reimburse since Procrit is an FDA-approved drug used in treatment of covered service; but there is more and more management of its use

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INFLUENCING PAYOR COVERAGE

Influencer	Comments
Clinical data <ul style="list-style-type: none"> • Label • Peer-reviewed literature • Third-party clinical review 	<ul style="list-style-type: none"> • Evidence-based clinical results are the foundation of every coverage discussion
Internal data <ul style="list-style-type: none"> • Claims experience • Input of payor's physician community through P&T 	<ul style="list-style-type: none"> • Actual experience carries significant weight
Guidelines <ul style="list-style-type: none"> • Compendia – especially for off-label use • M&R and other guidelines 	<ul style="list-style-type: none"> • Publicly-accepted practice guidelines are a common standard that shelters payors from liability
State government <ul style="list-style-type: none"> • Legislature • Regulatory 	<ul style="list-style-type: none"> • State government can impact coverage requirements through specific legislation or through the office of the State Insurance Commissioner
Federal government <ul style="list-style-type: none"> • Lobbyist/advisors (MedPac) • HCFA • FDA • Congress 	<ul style="list-style-type: none"> • Federal government decisions generally cascade down
General public <ul style="list-style-type: none"> • Educated large employers • Large consumer demand 	<ul style="list-style-type: none"> • Payors will respond to demands of their customers

While OBI must influence a broad set of constituents to influence payor coverage, the foundation of everything must be compelling clinical evidence

Implied strategy

- Design and carry out clear, unambiguous clinical trials supporting positioning
- Build support for coverage among multiple influencers

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INFLUENCING PHYSICIAN USAGE

Influencer	Comments	Implied strategy
Personal experience <ul style="list-style-type: none"> Initial training Ongoing experience Formulary status of drug 	<ul style="list-style-type: none"> Practice patterns are largely habitual unless given new compelling reason to change 	<ul style="list-style-type: none"> OBI must preserve positive economics for physicians If economics deteriorate <ul style="list-style-type: none"> Standard of care and "habitual" prescribing increases in importance Advocacy and patient push will be vital
Economics <ul style="list-style-type: none"> Drug Administration Office visit 	<ul style="list-style-type: none"> In today's world of medicine, dollars drive behavior, even in oncology 	
Clinical evidence <ul style="list-style-type: none"> Literature Thought leaders CME 	<ul style="list-style-type: none"> Physicians are trained to think analytically and to monitor clinical developments 	
Physician peer groups <ul style="list-style-type: none"> Practices Associations 	<ul style="list-style-type: none"> Practice patterns differ by locale and region 	
Pharma industry <ul style="list-style-type: none"> Sales reps CME Advertising 	<ul style="list-style-type: none"> Ability to educate physicians about Procrit's benefits Opportunity to assist in practice management to improve economics 	
Patients	<ul style="list-style-type: none"> Patient push may be stronger in oncology than other therapeutic areas Urgency of disease Payor/physician desired image for compassion 	

Source: Interviews

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UNIT PRICE REALIZATION – STRATEGIC IMPLICATIONS

Strategic opportunity	Example tactics
<ul style="list-style-type: none"> Monitoring and lobbying of Federal government at two levels: <ul style="list-style-type: none"> Key Executive Branch agencies (particularly HCFA, NCI and FDA) Politics of Capitol Hill Build more comprehensive relationships with oncology disease and patient advocacy groups to ensure strong reimbursement Recognize the interplay among AWP, discounts/ rebates and FSS and how they impact each other Standard of care 	<ul style="list-style-type: none"> Develop a wide net of contacts and foster ongoing conversations at multiple levels Develop relationships with key thought leaders in Congress, e.g., Allen, Stark, Kennedy, Rockefeller and Waxman Use existing relationships to leverage unique J&J position across oncology spectrum: <ul style="list-style-type: none"> Prevention Diagnosis Treatment Supportive care to be seen as a thought leader in disease rather than products Re-examine discretionary level of discounts strategic account managers may award Identify key decision makers to establish Profit as standard of care to physicians, payors, patients, societies, and all other influential parties

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APCs -- STRATEGIC IMPLICATIONS

Strategic opportunity	Example tactics
<ul style="list-style-type: none"> Promote cancer carve-out 	<ul style="list-style-type: none"> Work with key cancer community members to promote carve-out such as support of Medicare Full Access to Cancer Treatment Act; ensure carve-out will include payment for supportive care Consider aligning with other key oncology players such as BMS, particularly if there is a risk that they might choose to "go it alone" and "give up" supportive care coverage to ensure chemotherapy coverage
<ul style="list-style-type: none"> Increase value of chemotherapy APC to include cost of Procrit Standard of care 	<ul style="list-style-type: none"> Work with Medpac and others to lobby for specific changes in the way APCs are bundled and priced Establish Procrit as standard of care so that out-patient clinics will have a harder time eliminating Procrit despite potential lack of room in capitated system

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MEDICARE NATIONAL COVERAGE – STRATEGIC IMPLICATIONS

Strategic opportunity	Tactics
<ul style="list-style-type: none"> Standard of care Shape discussion around clinical use and standards on state, local, and private payor levels 	<ul style="list-style-type: none"> Understand and influence the process to establish Procrit as standard of care for all MCAC members <ul style="list-style-type: none"> Develop strategies to ensure each member understands the clinical value of Procrit Understand and communicate with full set of external advisors who could be brought in for technical assessment Proactively provide relevant and persuasive fact base to key influencers and decision makers Consider focusing guideline discussion on oncology if push for all indications is perceived as "greedy"

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MEDICAL TO PHARMACEUTICAL SWITCH – STRATEGIC IMPLICATIONS

Strategic opportunity	Example tactics
<ul style="list-style-type: none"> Establish Procrit as standard of care to all relevant parties 	<ul style="list-style-type: none"> Ensure compendia listings are as strong as possible Lobby state legislatures to adopt compendia Work more closely with individual and institutional thought leaders
<ul style="list-style-type: none"> Encourage full disease management for total care of oncology, HIV, and surgery patients 	<ul style="list-style-type: none"> Work with disease management companies and leading oncology companies (e.g., AOR) to develop disease management programs which include Procrit
<ul style="list-style-type: none"> Discourage risk sharing programs by payors which encourage physicians to decrease prescribing 	<ul style="list-style-type: none"> Align with advocacy groups to pass legislation to discourage risk sharing for oncology which might encourage reduced pharmaceutical usage

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STATE LEGISLATIVE AND REGULATORY ACTIVITY – STRATEGIC IMPLICATIONS

Strategic opportunity	Example tactics
<ul style="list-style-type: none"> • With "patients' rights" bills, promote cancer "quality of life" care coverage mandate <ul style="list-style-type: none"> – Pain management – Nausea management – Fatigue management • Explore opportunities to work with state insurance commissioners and Department of Corporations to ensure most attractive regulatory guidelines 	<ul style="list-style-type: none"> • Work with key cancer community members (both other product companies and patient advocacy groups) to promote mandate • Educate key state legislators and staff on the "cancer care case" • Work with key cancer community members to educate key regulators and their staff about "the cancer care case"

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LOCAL LEGISLATION/REGULATION – STRATEGIC IMPLICATIONS

Strategic opportunity	Example tactics
✓ • Develop relationships with key decision makers at leading private plans (including special focus on Medicare Risk leading plans e.g., Humana, Pacificare, Kaiser, United)	✓ • Call on local medical directors in addition to case managers
✓ • Develop relationships with key decision makers at local Medicare Carriers in critical states	✓ • Call on local medical directors in addition to case managers
• Develop Procrit as standard of care	• Establish Procrit as standard of care so that it is "unacceptable" not to cover or to have restrictive guidelines
• Better integrate payor contracting approach	• Coordinate contracting across entire product line (HMO, PPO, Medicare Risk) for key payors • Rethink pricing decisions based on impact on AWP (e.g., discounts, rebates)

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ORGANIZATIONAL IMPLICATIONS OF PHASE 1

- Increase in over-all resource levels particularly on private and state level
- Realigned structure and reporting relationships
- Change in roles/activities to enhance focus on:
 - Tiered decision makers
 - Long term relationships
 - External networking/alliance building
- Expanded Strategic Customer Group interactions within OBI and J&J particularly:
 - Clinical and regulatory
 - Field sales force
 - J&J federal and state groups
- Increased group skill set:
 - Clinical/medical knowledge and credibility
 - Prioritization and focus
 - Customer relationships beyond traditional sales and contracting

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